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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,274	10/06/2003	Jeffrey Richard Jackson	PF563D4	1009

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EXAMINER

WILDER, CYNTHIA B

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 03/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/678,274	Applicant(s) JACKSON ET AL.	
	Examiner Cynthia B. Wilder, Ph.D.	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-20 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 1-9 and 19-20, drawn to an isolated polynucleotide, host cell and vector, classified in class 536, subclass 23.1.
 - II. Claims 10, 11, drawn to an isolated polypeptide, classified in class 530, subclass 350.
 - III. Claim 12, drawn to antibody, classified in class 424, subclass 130.1
 - IV. Claims 13-14, drawn to a method of treating a subject, class 514, subclass 44.
 - V. Claims 15, drawn to a hybridization assay for diagnosing disease, class 435, subclass 6.
 - VI. Claims 16-18, drawn to a ligand binding assay for identifying agonist and antagonist, class 435, subclass 7.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are unrelated products. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different structure and function. For example, invention I is drawn to an isolated polynucleotide which is composed of nucleotides and functions in methods of nucleic acid hybridization and amplification whereas invention II is drawn to an isolated polypeptide

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which is composed of amino acids linked by peptide bonds and arrange in complex combinations of alpha helices, beta pleated sheets, hydrophobic and hydrophilic domains. The polypeptide can function as fusion proteins with enzymatic functions or in ligand/receptor binding assays. Invention III differs from the other inventions in that invention III is drawn to an antibody which is composed of amino acids linked by peptide bonds. Antibodies are glycosylated and their tertiary structure are unique, where four subunits associated via disulfide bonds form into a Y-shaped symmetric dimer. The antibodies can function in immunoassays. Furthermore, searching the inventions of groups I, II and III together would impose a serious search burden. In the instant case, the search of the polynucleotide, the polypeptide and the antibody are not coextensive. The inventions of Groups I, II and III have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide and visa versa. Similarly, there may have been "classical" genetics papers, which had no knowledge of the polypeptide or antibody but spoke on the gene. The polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of group III. Furthermore, antibodies which bind to an epitope of a polypeptide may be known even if a polypeptide is novel. Antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target. Searching, therefore is not

coextensive for the different inventions of Groups I, II and III. The search of each invention of Groups I, II and III requires an extensive analysis of the art retrieved in a sequence search and will require an in-depth analysis of technical literature. As such, it would be burdensome to search the inventions of groups I, II and III together.

2. Inventions I, II, III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide, polypeptide and antibody of Groups I, II and III can be used in another materially different process besides in a method of treatment of a subject. For example, the polynucleotide can be used in methods of nucleic acid amplification or in methods of nucleic acid cloning or in aptamer studies. The polypeptide and antibody can be used in mutagenesis assays or two-hybrid systems or in immunoprecipitation assays.

3. Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide of invention I can be used in a materially different process besides in a hybridization method for diagnosing a disease. For example, the

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polynucleotide can be used in nucleic acid cloning and purification procedures or in antisense or aptamer studies.

4. Inventions II, III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptide and antibody can be used in a materially different process than in a method of identifying a compound. The polypeptide and antibody can be used in methods of mutagenesis or in two-hybrid systems or in immunoassays, such as in immunoprecipitation.

5. Inventions IV, V and VI are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation leading to different effects. For example, the method of invention IV is drawn to a method of treatment of a subject by administering a therapeutically effective amount of an agonist or antagonist, whereas the method of invention V is drawn to a hybridization assay for diagnosing a disease or a susceptibility to a disease and the method of invention VI is drawn to a method for identifying a compound using a ligand binding assay. The different methods have different method steps

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resulting in different objectives. The searches of the different methods are not coextensive because the different method comprises non-overlapping subject matter.

6. Because these inventions are distinct for the reasons given above and the search required for any one Group is not required for any other Group, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner works a flexible schedule and can be reached by phone and voice mail. Alternatively, a request for a return telephone call may be emailed to cynthia.wilder@uspto.gov. Since email communications may not be secure, it is suggested that information in such request be limited to name, phone number, and the best time to return the call.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Cynthia Wilder
CYNTHIA WILDER
PATENT EXAMINER
2/22/08